Remarks/Arguments

A. Status of the Claims

Claims 43, 50-51, 57-64, and 71 are amended. Claim 48 is cancelled. Support for the amendments can be found throughout the specification and claims as originally filed (*see*, *e.g.*, specification at 2, lines 7-12).

Claims 43, 44, 46, and 49-73 are pending, with claims 54 and 56-64 currently withdrawn from consideration as being directed to non-elected species. Applicant requests that the withdrawn claims be reintroduced in view of the fact that independent claim 43 is an allowable generic claim (see arguments below).

B. The Indefiniteness Rejections Are Overcome

Claims 43, 44, 46, 48-53, 55, 65-69, 72, and 73 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner contends that "the preamble recites a method of inducing apoptosis, but the steps of the method do not result in induction of apoptosis." Applicant disagrees with the rejection, as a person of ordinary skill in the art would understand the scope of this claim when read in light of the specification. However, in an effort to further prosecution and secure prompt allowance, the preamble phrase is now in the body of claim 43. This rejection is moot, and Applicant requests that it be withdrawn.

Claims 48, 50, 51, and 71 are rejected for indefiniteness in view of antecedent basis issues. Applicant notes that these claims have been revised to address the Examiner's concerns. Therefore, these rejections are moot, and Applicant requests that they be withdrawn.

C. The Anticipation Rejection Is Overcome

Claims 43-44, 46, 48-50, 52, 65-66, and 72 are rejected under 35 U.S.C. § 102(b) as being anticipated by Imler in light of Gilardi *et al.* The Examiner contends:

> Imler reviews adenoviral vectors used as vaccines. Imler shows adenoviral vectors comprising substitutions in the E1A-E1B region in figure 3 and Table 1. Imler shows in Table 1 that the vaccines generate various levels of response after administration to mammalian hosts.
>
> Gilardi et al. show in the abstract that the E4 region is inducible by E1A adenoviral proteins.

Action at 3-4.

Applicant disagrees with the rejection. The claims prior to any amendments made above are not anticipated by the cited references. The pending claims are also not anticipated because every element of Applicant's invention is not disclosed by Imler. *See Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001).

Independent claim 43 recites "[a] method of inducing apoptosis in a cell comprising administering to the cell an adenoviral vector comprising at least one essential viral gene or gene element under the control of a heterologous inducible promoter, wherein the vector lacks a functional copy of one or more of an E1B, E2A, E2B, or E4 gene or gene element, and wherein apoptosis is induced in the cell." The cited reference fails to disclose or suggest at least two aspects of Applicant's claimed invention:

1. "at least one essential viral gene or gene element under the control of a heterologous inducible promoter;" and
2. "wherein apoptosis is induced in the cell."

Imler appears to concern the use of "[a]denovirus vectors as recombinant viral vaccines." Imler at 1143 (Title). The author explains "[t]his article reviews the main properties of adenoviruses which render them attractive for vaccine development, as well as the results of the immunization studies performed to date." *Id.* at 1143 (Abstract). There does not appear to be any discussion in this reference of using a heterologous inducible promoter or inducing apoptosis in a cell.

Further, Gilardi *et al.* does not supplement Imler's deficiencies. This reference appears to be cited only for the proposition that "the E4 region is inducible by E1A adenoviral proteins." Action at 4; *see also* MPEP § 2131.01 ("...a 35 U.S.C. 102 rejection over multiple references has been held proper when the extra references are cited to...[s]how that a characteristic not disclosed in the reference is inherent."). Applicant also notes that there is no motivation to combine these references to induce apoptosis in a cell, as the teachings of Imler appear to concern using adenovirus to provoke an immune response in a mammal. Imler at Abstract; *see also* MPEP § 2143.01 ("Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so.").

In conclusion, the combination of Imler with Gilardi *et al.* does not lead to Applicant's claimed method comprising an "...adenoviral vector comprising at least one essential viral gene or gene element under the control of a heterologous inducible promoter...and wherein apoptosis is induced in the cell." Therefore, the present anticipation rejection cannot be maintained and should be withdrawn. *See Telemac Cellular Corp.*, 247 F.3d at 1327.

D. The Obviousness-Type Double Patenting Rejections Are Overcome

Claims 43, 44, 48-53, 55, and 65-67 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 3-14 of U.S. Patent No. 6,630,344 ('344 Patent) in view of claims 1, 2, 17, 31, and 32 of U.S. Patent 6,899,870. Applicant is concurrently filing a terminal disclaimer for the '344 Patent. Therefore, this rejection is moot, and Applicant requests that it be withdrawn.

E. Conclusion

The present claims are in a condition for allowance, and such favorable action is requested. The Examiner is invited to contact the undersigned Attorney at (512) 536-3020 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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